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May 27, 1997

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street S.W. Washington, DC 20204

0161 '97 SEP 19 P1:45

## Section 403(r)(6) Notification

Dear Sir or Madam:

In response to the courtesy letter received on November 19, 1996 from the FDA, suggesting that our previous statement for this product was a drug claim, LEINER HEALTH PRODUCTS notifies FDA that it is resubmitting the following restructured statement in accordance with the requirements of section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act:

## **Aids Digestion**

Ginger is a nutritious root which has world wide usage as an aid to normal digestive activity. As a supplement, its unique aromatic compounds can also help maintain stomach equilibrium.

on the following product:

Your Life® Ginger

Very truly yours,

LEINER HEALTH PRODUCTS

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs

William Cochran, Regulatory Affairs